K071100

Section 5. 510(k) Summary

5.1. 510(k) summary information:

OCT 15 2007

5.1.1.

5.1.1.1. **Submitter's name:** Common Sense Ltd

5.1.1.2. **Address:** 7 Haeshel St, Caesarea 38900, POB 3567, Israel

5.1.1.3. **Telephone:** 972-4-6277101, Fax: 972-4-6277103

5.1.1.4. **Contact person:** Menashe Terem, CEO

5.1.1.5. **Date: April 25, 2007, Rev. October 11, 2007**

5.1.2.

5.1.2.1. **Name of the device:** AmniScreen™ Home Detection Liner Kit

5.1.2.2. **Classification name: Urinary pH (nonquantitative) test system**

5.1.3. **Identification of the legally marketed predicate device:**
AMNIOTEST(TM), 510(k) no: K914419

5.1.4. **A description of the device:** The AmniScreen™ Home Detection Liner Kit contains a Testing Panty-Liner (TPL) and a Drying Tray (DT). The TPL comprises a regular panty-liner and an indicator strip assembled into the panty-liner, covered with two layers of one-way perforated film. The indicator strip is removed after use and placed in the DT for 30 minutes before reading the test results. When the indicator strip has been in contact with amniotic fluid, the user will observe a blue-green stain on the yellow background of the strip. An elevated pH level of the fluid causes the stain. The stains on the strip are caused by the sensitivity of a proprietary polymer, which coats the strip and contains the traditional indicator – Nitrazine Yellow, to pH levels above 5.2 units. The proprietary polymer is also sensitive to certain concentrations of ammonium in the tested fluid, and when the color changes are created by fluids with a certain concentration level of ammonium, and pH levels up to 7.0 units, these color changes are reversible and during a drying period of 30 minutes the blue-green stains fade back to yellow.

5.1.5. **The intended use of the device:** The AmniScreen™ Home Detection Liner Kit is intended to detect possible leakage of amniotic fluid when vaginal wetness is experienced during pregnancy by indicating pH level. pH levels greater than or equal to 5.2 produce a blue-green color. Patients are instructed to report or show test results to their healthcare provider for interpretation and medical care.

5.1.6. Technological characteristics comparison of AmniScreen™ Home Detection Liner Kit vs. Predicate Device:

Characteristic	**AmniScreen™ Home Detection Liner Kit**	**AMNIOTEST™**
Sample collecting device	Panty-liner	Swab
Sample collecting Method	Passive, non-invasive	Active, invasive
Duration of test	Up to 12 hours	15 seconds
Chemical parameters	pH	pH
Result reading	Blue-green stain on yellow background	Comparing to a color scale
Urine Interference	Urine with pH level more than 7.0 units	None
Sensitivity	Detects intermittent leaks that may be undetectable by Standard Clinical Diagnosis 95.65% based on pivotal study results	
Specificity	84.46% based on pivotal study results	
Interference	Interference from urine with pH levels of 7.0 and above, and from BV with pH levels of 5.0 and above	Interference from sampling, and from BV with pH level of 6.5 or above

510(k) Summary Performance data:

5.1.7. Non-clinical tests: Lab tests to prove efficacy and pH cutoff were performed in the developer's labs and are performed on every batch as part of the manufacturing QC. Reference safety tests were performed by laboratories holding certificates to test for cyto-toxicity, irritation and sensitization (see section 15). Biological bio-burden tests were performed in the developer's labs and are performed as part of the manufacturing QC. Shelf life, storage, temperature limits and transportation tests were performed in the developer's labs.

5.1.8. Clinical tests: 339 pregnant participants, arriving at hospitals at three different test sites sensing unexplained wetness, were enrolled in a clinical study to test AmniScreen™. Two of the participants reported of being very uncomfortable when performing the test. The users or the trained staff encountered no safety issues. Two of the participants reported they had a problem using the AmniScreen™ Home Detection Liner Kit or reading the results. The correlation between the result readings by the participants and trained staff exceeded 97.4%, and there was no significant effect of the result-reading source on the performance of the AmniScreen™ (i.e., sensitivity and specificity achieved by both are almost identical). The sensitivity and specificity of the AmniScreen™ Home Detection Liner Kit in the study were substantially equivalent to predicate device performance, which was demonstrated by a Nitrazine Paper test performed by clinicians.

5.1.9. The conclusions drawn from the non-clinical and clinical tests: From the biocompatibility tests it can be concluded that the AmniScreen™ Home Detection Liner Kit complies with the required safety standards regarding cyto-toxicity, irritation and sensitization. The AmniScreen™ Home Detection Liner Kit may be mechanically safer to the user than AMNIOTEST™ as it is not inserted into the vagina. From the pivotal clinical study it can be concluded that the sensitivity and specificity of the AmniScreen™ Home Detection Liner Kit are substantially equivalent to the predicate device. From the comparison of staff result reading to patient readings, it can be concluded that the AmniScreen™ Home Detection Liner Kit is acceptable to be used as a home test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Common Sense Ltd.
c/o Heller Ehrman, LLP
1717 Rhode Island Avenue, N.W.
Washington, DC 20036
Attn: Ms. Natasha Leskovsek

OCT 15 2007

Re: k071100
Trade/Device Name: AmniScreen™ Home Detection Liner Kit
Regulation Number: 21 CFR§862.1550
Regulation Name: Urinary pH (nonquantitative) test system.
Regulatory Class: Class I
Product Code: CEN
Dated: September 12, 2007
Received: September 13, 2007

Dear Ms. Leskovsek:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K071100

Device Name: AmniScreen™ Home Detection Liner Kit

Indication For Use:

The AmniScreen Home Detection Liner Kit is intended to detect possible leakage of amniotic fluid when vaginal wetness is experienced during pregnancy by indicating pH level. pH levels greater than or equal to 5.2 produce a blue-green color. Patients are instructed to report or show test results to their healthcare provider for interpretation and medical care.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K071100